CONSENT FORM *OUTLINE*

I. General purpose of the study:

Why are you conducting this study? What do you hope to gain from this study? Why should subjects participate?

II. Procedure:

How and where will the study be conducted? Who will be conducting the study? What will the subject be expected to do? How much of the subject's time is needed?

III. Disclosure of risks/description of benefits:

As appropriate, state whether risks involved in participation are minimal, or if the project involves more than minimal risk. Describe in detail all potential risks of the study, and procedures to minimize risks. List any direct/indirect benefits to the subject.

IV. Confidentiality:

What level of confidentiality will be afforded to subjects? How will confidentiality be protected? Who will have access to the data, how will the data be protected, and how long will the data be kept? Will the data be used for research purposes at any time other than the purpose(s) stated above?

V. Freedom of consent:

Include a statement such as: "My participation (my child's participation) is voluntary and my (my child's) refusal to participate will not involve penalty or loss of benefits to which I am (my child is) otherwise entitled, and I (my child) may discontinue participation at any time without penalty or loss of benefits to which I am (my child is) otherwise entitled."

For studies involving classroom students: "I understand that my (my child's) refusal to participate or my (my child's) withdrawal at any point will not affect my (my child's) course grade or class standing."

This statement should be written in language appropriate for the age and level of education of the subjects.

VI. Questions about the research:

Include name, address and phone number where principal investigator/faculty advisor can be reached during normal business hours.

_____ _____

Participant signature Date

VII. Parental consent required for all subjects under 18 years of age.

EXAMPLE:

As parent or legal guardian, I hereby give my permission for _____ to participate in the research described above.

_____ _____

Parent/legal guardian signature Date

Consent Form Checklist:

- A statement that the study involves research, an explanation of the purpose of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A detailed and specific description of any potential risks or discomforts to the subject. The consent form should state that minimal risk is involved when the proposed research is viewed as involving little or no forseeable risk to human subjects.
- A description of any benefits to the subject or to others which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- A statement describing how and to what extent confidentiality of records identifying the subject will be maintained, including who will have access to the data, for what purposes, how the data will be stored, and for how long.
- For research involving more than minimal risk, an explanation as to whether any compensation will be provided and an explanation as to what medical treatments will be provided if injury occurs and, if so, what they consist of, who will be responsible for medical expenses, and where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about the research, including a UW department, principal investigator's name, faculty advisor name if an undergraduate or graduate student is the investigator, and phone number.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. To obtain effective informed consent, the statement regarding voluntary participation must be understood by the person (subject) giving their consent, whether for themselves, or on behalf of their child. To insure that the voluntary nature of a subject's participation is fully understood, the voluntary statement must be written in age/education appropriate language. **THE FREEDOM OF CONSENT STATEMENT APPLIES TO ALL TYPES OF PROJECTS AND MUST APPEAR ON THE CONSENT FORM or OTHER INFORMATION THAT WILL BE GIVEN TO THE PARTICIPANTS.** For research involving children, it should be clear that the child subject will be free to refuse to participate and may withdraw participation at any time during the study.
- Description of how a subject may withdraw their participation
- If appropriate, a statement that the particular treatment or procedure may involve risks which are currently unforeseeable
- If appropriate, anticipated circumstances under which a subject's participation may be terminated by the investigator

- If appropriate, any additional costs to the subject that may result from participation in the research
- If appropriate, the consequences of a subject's decision to withdraw
- Space for signature of subject and space for signature of parent for subjects under 18 years of age unless waived by the IRB. The IRB may require the assent of a minor subject in addition to the consent of the parent or guardian.